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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/421,635	10/19/1999	MARK A. REILEY	1759.16690	4414

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EXAMINER

MAYNARD, JENNIFER J

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 12/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/421,635

Applicant(s)

REILEY

Examiner

Jennifer J Maynard

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 September 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 14. 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

Claim Rejections - 35 USC § 102/Claim Rejections - 35 USC § 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-13, 18-23, 25, 33-38 and 41 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Strasser et al. (US 4,838,282 A).

Strasser et al. disclose a tool comprising a first instrument (14) having a first handle (16), and a second instrument (12) having a second handle (18); both instrument handles are disclosed as being made of an ABS thermoplastic molding material (e.g. "Cycolac") see Column 5, lines 24-27. Additionally, Strasser et al. disclose a first marker (i.e. projection) (16.6) and a second marker (i.e. slot) (18.6) which unidirectionally mate the first instrument handle (16) and the second instrument handle (18) thus ensuring proper bevel alignment between the sharpened distal end edge (12.1) of the second instrument (12) and the sharpened distal tip (14.1) of the first instrument (14) and prevents undesirable relative rotation between the first instrument and the second instrument during use, see Column 4, line 62 through Column 5, line 3.

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The Examiner references Applicant's specification with regard to identifying material compositions, which are heat-sensitive, deformable materials, i.e. Lustran. It was well known in the art that Lustran was categorized as an ABS (Acrylonitrile-Butadiene-Styrene) thermoplastic. Strasser et al.'s thermoplastic molding material is also an ABS, however the trade name given is that of Cicolac.

It is inherent that ABS materials have identical or extremely similar physical traits thus Applicant's claim language is anticipated by Strasser et al.'s device.

In the alternative, it would have been a matter of obvious design choice to one having ordinary skill in the art at the time the invention was made to have manufactured Strasser et al.'s handles out of Lustran, as both Cicolac and Lustran are ABS thermoplastic materials and would be interchangeable as they both have the same physical properties.

With reference to Applicant's claimed first and second markers, in the alternative to Strasser et al.'s tang and slot, Cerny (US 5,385,561 A) discloses an injection device comprising a first instrument (10) with a first marker (i.e. embossed graphics) (56) on a handle portion (18) and a second marker (i.e. longitudinal stripe) (38) on a cannula portion (12). It would have been obvious to one having ordinary skill in the art to have utilized the embossed graphic-type or stripe-type markers on the handle portion(s) of Strasser et al., as taught by Cerny, so as to provide an alternative mechanism for aligning the tips of the instruments relative to one another during insertion, as Strasser et al. stress the importance of proper bevel alignment.

With reference to Applicant's claimed first and second markers, in the alternative to Strasser et al.'s internal tang and slot, Mehl (US 4,487,209 A) discloses a biopsy device comprising a first instrument (12) with a first marker (i.e. detent locking groove) (42) on a

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handle portion (52) and a second instrument (14) with a second marker (i.e. elongated detent button) (30) on a cannula portion (12). It would have been obvious to one having ordinary skill in the art to have utilized the external detent and groove markers on the handle portion(s) of Strasser et al., as taught by Mehl, so as to provide an equivalent alternative mechanism for aligning the tips of the instruments relative to one another during insertion, as Strasser et al. stress the importance of proper bevel alignment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14-17, 22, 29, 32, 39 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strasser et al. (US 4,838,282 A) in view of Webster (4,820,755 A).

Strasser et al. discloses a tool comprising a first instrument (14) having a first handle (16), and a second instrument (16) having a second handle (18).

Webster discloses polymers, such as polyolefins, and especially polypropylene for use in making medical instruments having a radiochromic hindered phenolic stabilizer which results in a blue color change when subjected to a sterilizing dose of gamma irradiation.

It would have been obvious to one having ordinary skill in the art to have made the handle of Strasser et al.'s biopsy tool out of a polymer, such as polypropylene, which included a

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radiochromic hindered phenolic stabilizer, so as to ensure proper sterilization following use thus allowing for subsequent use without cross-contamination.

Claims 24, 26-28, 42 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strasser et al. (US 4,838,282 A) in view of Bhiwandker et al. (US 3,523,011 A).

Strasser et al. discloses a tool comprising a first instrument (14) having a first handle (16), and a second instrument (16) having a second handle (18).

Bhiwandker et al. disclose a sterilization indicator material and tape containing the same for application to medical or surgical instruments. The indicator reacts with steam utilized during the sterilization process.

It would have been obvious to one having ordinary skill in the art to have applied Bhiwandker et al.'s indicator to the handle of Strasser et al.'s biopsy tool, so as to provide means for indicating that proper sterilization heat had been applied to the instrument thus allowing for subsequent use without cross-contamination.

Claims 27, 30, 31, 32, 39, 40, 42 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strasser et al. (US 4,838,282 A) in view of Olson (US 3,258,312 A).

Strasser et al. discloses a tool comprising a first instrument (14) having a first handle (16), and a second instrument (16) having a second handle (18).

Olson discloses a sterilization indicator material for monitoring adequate diffusion of ethylene oxide for application to medical or surgical instruments. The indicator reacts with ethylene oxide utilized during the sterilization process, resulting in a color change.

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It would have been obvious to one having ordinary skill in the art to have applied Olson's indicator to the handle of Strasser et al.'s biopsy tool, so as to provide means for indicating that proper diffusion of ethylene oxide had occurred during sterilization of the instrument thus allowing for subsequent use without cross-contamination.

Response to Arguments

Applicant's arguments filed 03 September 2002 have been fully considered but they are not persuasive. As noted above in the amended 102/103 rejection, Strasser et al. does indeed teach first and second markers which assure proper alignment of the beveled edges of the first and second instruments. Alternatively, the Examiner has also relied upon Cerny as a teaching of using embossed graphics or stripes as markers for proper orientation of the needle orifice, and Mehl as a teaching of using an external groove and detent mechanism for proper alignment of the beveled edges of the two instruments.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer J Maynard whose telephone number is 703.305.1356. The examiner can normally be reached on Mondays-Fridays 9:30 AM-5:30 PM; 1st Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703.308.3552. The fax phone numbers for the organization where this application or proceeding is assigned are 703.872.9302 for regular communications and 703.872.9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.308.0858.

J Maynard
December 2, 2002



BRIAN L. CASLER
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